

recite this subject matter, as discussed with the Examiner during an Interview. The specification supports new claims 107-108 at page 33, lines 11-30.

Upon entry of this amendment, claims 72-78, 82-87, and 104-108 will be pending in this application.

Interview Summary

Applicant thanks the Examiner for the interview of April 27, 2000, with the undersigned. The Examiner indicated during the interview that Applicant's arguments "appear to support a two-way test." (Examiner Interview Summary Record of April 27, 2000.) If this were true and only provisional rejections remained, the Examiner further indicated that "suspension of the application may be appropriate. (*Id.*)¹

Double patenting rejections over claims of later-filed applications

The Examiner rejected or provisionally rejected claims 72-79, 82-84, and 104-106 under the doctrine of obviousness-type double patenting over the following claims contained in later-filed applications: (1) claims 135-141, 143-154, and 156-164 of copending Application Serial No. 08/334,797 in view of Salser et al.; (2) claims 1-25 of U.S. Patent No. 5,994,127 (Application Serial No. 08/334,455); (3) pending claims of

¹ The Examiner also indicated during the interview that the proposed amendments attached to the Examiner Interview Summary Record of April 27, 2000, as Exhibit 1 overcame the § 112, second paragraph; § 102(b), § § 102(a)/103; and § 103 rejections. (See Examiner Interview Summary Record of April 27, 2000.) Although these rejections were only pending in application Serial No. 08/465,596, not in this application, they were mentioned in the Examiner Interview Summary Record because one record was prepared for both applications.

copending Application Serial No. 08/446,909; and (4) claims 1-84 of U.S. Patent No. 5,968,502 (Application Serial No. 08/451,894). (Paper No. 24 at pp. 4-6.) The Examiner again conceded that these rejections would be withdrawn if a two-way obviousness test were applied. (Paper No. 24 at p. 8.)

The Examiner noted that a two-way test "is applied only when Applicants could not have filed the claims in a single application and when there is administrative delay." (Paper No. 24 at p. 8.) It is apparent from Paper No. 24, as well as the interview, that the Examiner is satisfied that "Applicants could not have filed the claims in a single application." The Examiner decided, however, that sufficient "administrative delay" is not present because Applicant refiled the present application as a continuation application after having filed the asserted applications, even though the present application is entitled to an earlier effective filing date than the asserted applications. (Paper No. 24 at p. 8.) In other words, the only reason the Examiner provided for not applying a two-way test was her refusal to consider the effective filing date of the present application. The Examiner confirmed during the interview that, if the effective filing date of the present application were considered, a two-way test would apply, and she indicated that Applicant's arguments "appear to support a two-way test." (Examiner Interview Summary Record of April 27, 2000).

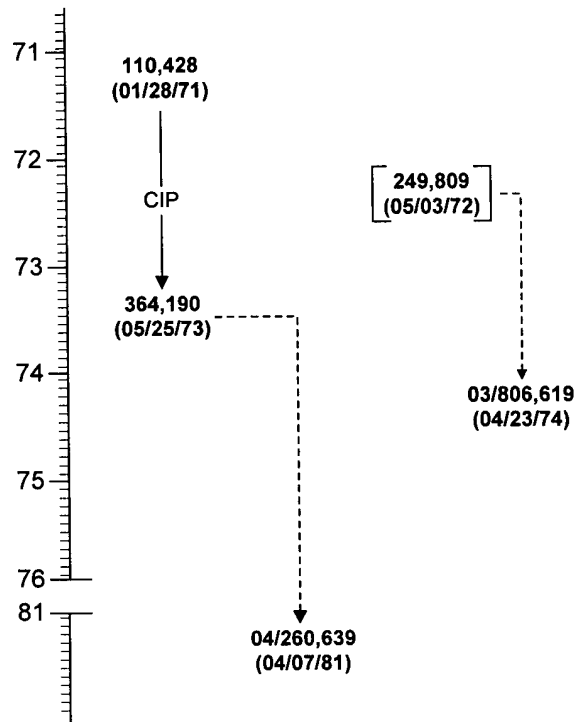
Applicant respectfully disagrees with the Examiner's refusal to consider the effective filing date of the present application. Although § 804(II)(B)(1) of the M.P.E.P. does not expressly address the issue of whether effective filing dates are to be considered in deciding whether to apply a two-way obviousness test, it cites two cases

from the Court of Appeals for the Federal Circuit as examples of proper application of the two-way test, and the Federal Circuit considered the effective filing dates in both these cases.

The M.P.E.P. states that, although "it may be very difficult to assess whether an applicant or the administrative process is primarily responsible for a delay in the issuance of a patent . . . the reasons for the delay in issuing a patent have been considered in assessing the propriety of a double patenting rejection." M.P.E.P. § 804(II)(B)(1)(b) at 800-19, cols. 1-2. The M.P.E.P. then states that in *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992) (copy attached), the Federal Circuit "did not hold the patentee accountable for a delay in issuing the first filed application until after the second filed application issued as a patent, even where the patentee had intentionally refiled the first filed application as a continuation-in-part after receiving a Notice of Allowance" *Id.* at col. 2.

The Federal Circuit in *General Foods* did not discuss which filing date is to be considered in deciding whether to apply a two-way test. However, an analysis of *General Foods* reveals that the Federal Circuit considered the effective filing date of the "first filed application." As the following chart shows, the "first filed application" in *General Foods* was filed on May 25, 1973, as a continuation-in-part of an application filed on January 28, 1971. *General Foods*, 23 U.S.P.Q.2d at 1841. The "second filed application" in *General Foods* was filed on May 3, 1972. See U.S. Patent No. 3,806,619.

General Foods²



If the effective filing date of the "first filed application" (January 28, 1971) were not considered, the "first filed application would have had a later filing date (May 25, 1973) than the "second filed application" (May 3, 1972). Thus, the "first filed application" of *General Foods* could only have been considered the first filed if its effective filing date was considered by the Federal Circuit.

² Applicant files herewith a copy of *General Foods* with supporting passages highlighted for all the facts in this chart except those in brackets. Applicant also files herewith a copy of U.S. Patent No. 3,806,619 with supporting passages highlighted for the facts in brackets.

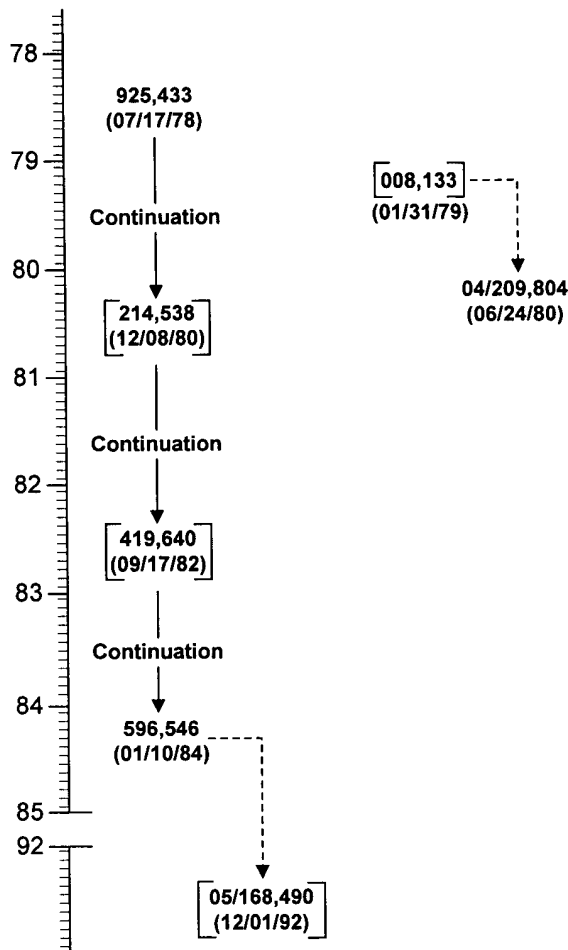
The M.P.E.P. goes on to state that "where, through no fault of the applicant, the claims in a later filed application issued first, an obviousness-type double patenting rejection is improper, in the absence of a two-way obviousness determination," citing *In re Braat*, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991) (copy attached). As in *General Foods*, the Federal Circuit in *Braat* did not discuss which filing dates are to be considered in deciding whether to apply a two-way test. However, an analysis of *Braat* reveals that the Federal Circuit again considered the effective filing date of the "first filed application."

The "first filed application" in *Braat* was filed on January 10, 1984, *id.* at 1289, but was entitled to an effective U.S. filing date of July 17, 1978, *id.* at 1290, through two continuation applications, one filed September 17, 1982, and the other filed December 8, 1980. The "second filed application" was filed on January 31, 1979. *Id.* These dates are compared in the following chart.

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Braat³



If the effective filing date of the "first filed application" (July 17, 1978) were not considered, the "first filed application" would have had a later filing date (January 10, 1984) than the "second filed application" (January 31, 1979). Thus, the "first filed

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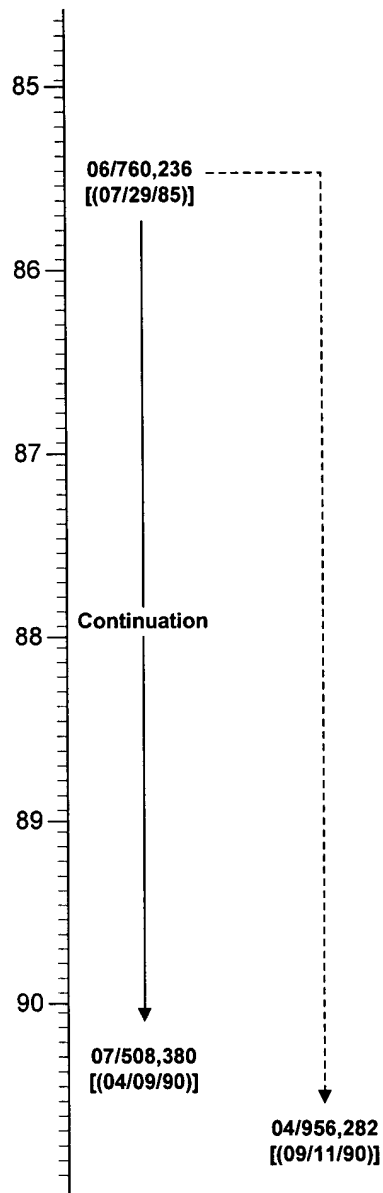
Applicant files herewith a copy of *Braat* with supporting passages highlighted for all facts in this chart except those in brackets. Applicant also files herewith a copy of U.S. Patent Nos. 4,209,804 and 5,168,490 with supporting passages highlighted for the facts in brackets.

application" of *Braat* also could only have been considered the first filed if its effective filing date was considered by the Federal Circuit.

Accordingly, although the M.P.E.P. does not expressly so state, Federal Circuit precedent and the M.P.E.P.'s citation of it show that the filing date to be considered in determining whether to use a one-way or a two-way test for nonobviousness-type double patenting is the effective filing date. As the Examiner confirmed during the interview, consideration of Applicant's effective filing date would require a two-way test, and application of a two-way test would result in withdrawal of these actual and provisional rejections.

The Examiner indicated during the interview that the refusal to consider the effective filing date of the present application was based upon the citation by the M.P.E.P. of *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993). Applicant respectfully submits that reliance upon *Goodman* is misplaced. Neither *Goodman* itself nor the M.P.E.P.'s citation of *Goodman* makes any mention of considering or not considering the effective filing date of the application at issue. Indeed, consideration or not of the effective filing date in *Goodman* could not have affected the decision because the application at issue in *Goodman* (07/508,380) was a continuation of the application whose issued claims were cited against it, 29 U.S.P.Q. 2d at 2012, as the following chart shows:

Goodman⁴

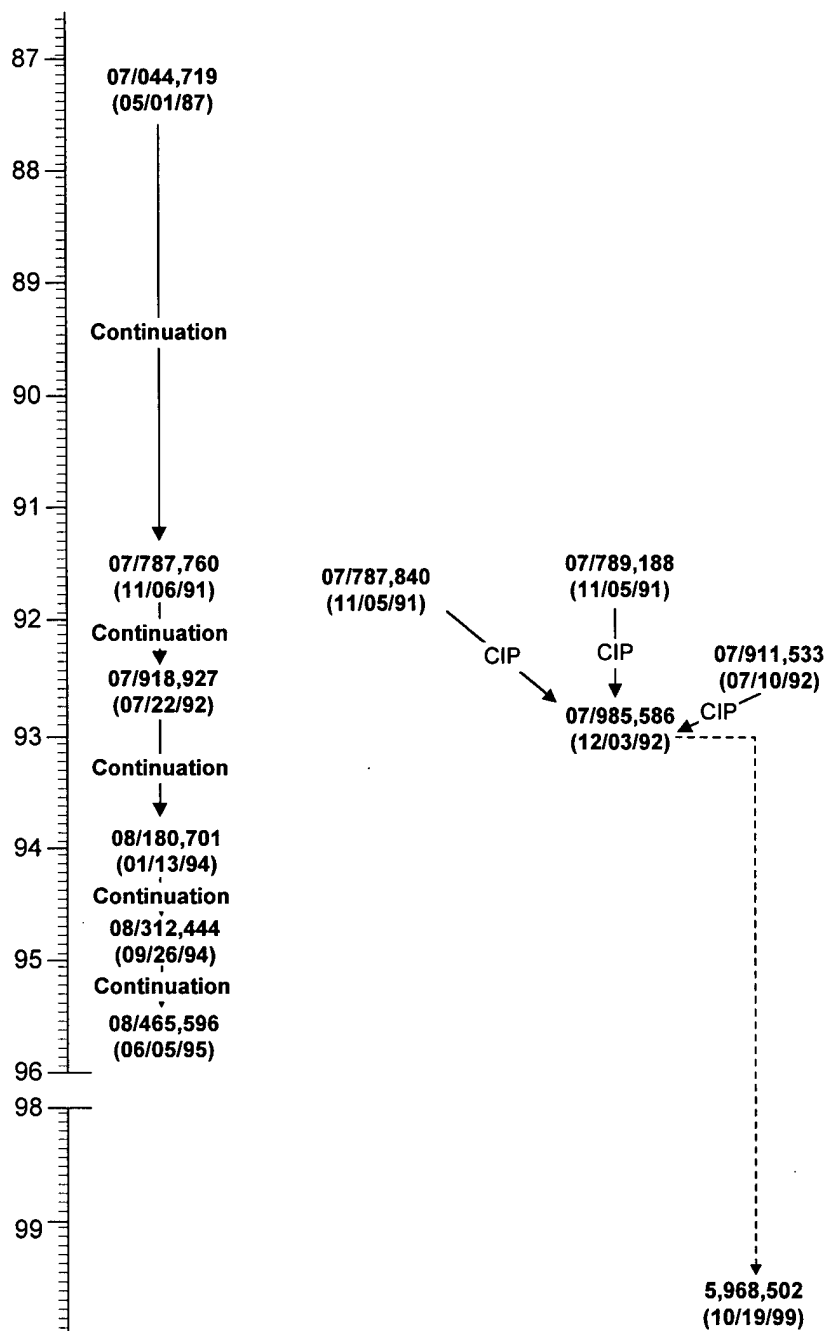


⁴ Applicant files herewith a copy of *Goodman* with supporting passages for all facts in this chart highlighted except those in brackets. Applicant also files herewith a copy of a Derwent patent family printout for the patent and applications involved in *Goodman* with supporting passages highlighted for the facts in brackets.

If the effective filing date were not considered, the application at issue in *Goodman* (07/508,380) would have been the later filed application. If the effective filing date were considered, the application at issue would have been filed the same day as the application whose claims were cited against it. A one-way test, however, would apply in both situations. M.P.E.P.'s 804(II)(B)(1)(a) ("If the application at issue is the later filed application or both are filed on the same day, only a one-way determination of obviousness is needed in resolving the issue of double patenting . . ."). Thus, the issue of considering the effective filing date or not was irrelevant in *Goodman*, and *Goodman* cannot possibly support a refusal to consider the effective filing date of the present application.

Moreover, the present situation is more analogous to *General Foods* and *Braat*, in both of which the Federal Circuit rejected double patenting attacks, than *Goodman*, in which the Federal Circuit upheld a double patenting attack. In *General Foods* and *Braat*, the cited patent claims had a later effective filing date than the first filed application and did not appear until the separately filed later application was filed. Similarly, in the present situation, the cited patent claims had a later effective filing date than the present application and did not appear until the separately filed later applications were filed, as the following chart shows.⁵

⁵ All the cited applications and patents claim benefit of application Serial No. 07/787,840, filed November 5, 1991. For clarity, Applicant only includes the first issued patent (5,968,502) in this chart. Applicant files herewith a highlighted copy of this patent.



In *Goodman*, in contrast, the cited patent claims had the same effective filing date as the first filed application and were pending in the first-filed application.

Goodman, 29 U.S.P.Q.2d at 2016. Accordingly, *General Foods and Braat*, in which the Federal Circuit found no obvious-type double patenting, apply to the present situation. Cf. M.P.E.P. § 2144 ("If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the Examiner may use the rationale used by the Court."). *Goodman*, in which the Federal Circuit found obviousness-type double patenting, does not. *Id.*

Because the Examiner's refusal to apply a two-way test was based solely upon not considering Applicant's effective filing date, a two-way test should be applied. Indeed, the Examiner indicated that these arguments "appear to support a two-way test." (Examiner Interview Summary Record of April 27, 2000.) As the Examiner indicated in Paper No. 24, application of the two-way test will result in withdrawal of these actual and provisional double-patenting rejections.

Double patenting rejections over claims of co-filed applications

The Examiner provisionally rejected claims 72-79, 82-84, and 104-106 under the doctrine of obviousness-type double patenting as being unpatentable over claims 91-103, 106-108, and 129-131 of copending application Serial No. 08/461,282 ("the '282 application"), over claim 44 of copending application Serial No. 08/460,902 ("the '902 application"), and over claim 36 of copending application Serial No. 08/465,582 ("the '582 application"), all of which were filed the same day as the present application. (Paper No. 24 at p. 3.) Because these are provisional rejections, Applicant need not respond to them until claims have been allowed in one of these applications.

Nonetheless, Applicant has previously argued that claims 72-79, 82-84, and 104-106 are patentable over the claims of the '582 application and the claims of the '902 application because claims 72-79, 82-84, and 104-106 are directed to a separately patentable species of the genus encompassed by the claims of the '582 and '902 applications. The Examiner rejected this argument for two reasons. First, the Examiner asserted that "a genus ('582 and '902) always renders a species (the instant application, '292⁶) obvious." (Paper No. 24 at p. 4.) Second, the Examiner asserted that, because "the '582 and '902 claims encompass" the species to which the present claims are directed, "the new claims limitations do not render the claimed invention as an unobvious species." (Paper No. 24 at p. 7.)

Applicant respectfully submits that both of these reasons reveal a misapplication of the law of obviousness to species claims. First, in *In re Jones*, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992), the Federal Circuit expressly rejected the PTO's argument "that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it." Second, as the M.P.E.P. states: "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." M.P.E.P. § 2144.08 II at 2100-124, col. 2 (citing *In re Baird*, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994).

This principle is especially applicable to double patenting rejections because domination and double patenting are two separate issues. M.P.E.P. § 804(II) at

800-16. Domination occurs when a patent or application has a generic claim that encompasses a species claim in another patent or application. *Id.* "Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection." *Id.*

It must be remembered that the patentability of a species over a genus "should be analyzed no differently than any other claim for purposes of 35 U.S.C. § 103." *Id.* at col. 1. In connection with this principle, Applicant has submitted much evidence showing that claims 72-79, 82-84, and 104-106 are directed to a separately patentable species (*ex vivo* gene transfer using nonviral techniques) from the genus encompassed by the claims of the '582 and '902 applications (*ex vivo* gene therapy), including a substantial body of prior art that teaches away from nonviral techniques. Although Applicant believes the Examiner has not properly considered this evidence, Applicant will not further address this issue here because prosecution of the present application should be suspended, as Applicant discusses below.

**Provisional § 102 (f), § 102 (g), or § 103
rejection over count and disclosure of winning interference party**

The Examiner provisionally rejected claims 72-79, 82-84, and 104-106 under 35 U.S.C. § 102(f), § 102(g), or § 103 over the count in the interference and the disclosure of the winning party in the interference. (Paper No. 24 at p. 9.) Because this is also a provisional rejection, Applicant need not respond to this rejection until claims have been allowed in the present application or the interference has terminated. Applicant notes,

however, that claim 44 of the '902 application and claim 36 of the '852 application are identical to the count of interference.

Suggestion for Suspension of Prosecution

Section 2315.01 of the M.P.E.P. states:

Where one of several applications of the same inventor or assignee which contain overlapping claims gets into an interference, the prosecution of all the cases not in the interference should be carried as far as possible, by treating as prior art the counts of the interference for the purpose of making provisional rejections and by insisting on proper lines of division or distinction between the applications.

(Emphasis added.) This is what the Examiner has done to date, allowing Applicant to prosecute this application as far as possible by not suspending prosecution and making provisional rejections over the count of the interference. However, as Applicant has shown above, the only remaining rejections in this application are provisional rejections (obviousness-type double patenting rejections over co-filed applications and § 102(f), § 102(g), or § 103 rejections over the count and disclosure of the winning party), so the prosecution of this application has been "carried as far as possible." If only provisional rejections remain, the Examiner indicated that "suspension of the application may be appropriate." (Examiner Interview Summary Record of April 27, 2000.)

Section 2315.01 sets forth Form Paragraph 23.17, which "must follow all rejections under 35 U.S.C. 102 or 103 using the count of an interference as prior art." ¶ 23.17, Examiner Note 1 (reproduced at M.P.E.P. § 2315.01 at 2300-28 through -29). Form Paragraph 23.17 reads as follows:

¶ 23.17 *Rejection Based on Count of an Interference*

The rejection of claim [1] above based on count [2] of Interference No. [3], to which applicant is a party, is a provisional rejection for the purpose of resolving all remaining issues in this application. The provisional assumption that the count is prior art under 35 U.S.C. § 102(g) against this application may or may not be true, and the prosecution in this case will be suspended pending final determination of priority in the interference if and when no other issues remain.

Examiner Note:

1. This paragraph must follow all rejections under 35 U.S.C. § 102 or 103 using the count of the interference as prior art.

Id. (Emphasis added.) The Examiner has rejected the pending claims "under 35 U.S.C. § 102 or § 103 using the count of the interference as prior art," and Applicant has shown that all of the other rejections should be withdrawn. Accordingly, prosecution of this application should be suspended by the Office.

Indeed, immediately after Form Paragraph 23.17, M.P.E.P. § 2315.01 sets forth Form Paragraph 23.18:

¶ 23.18 *Suspension of Prosecution Pending Outcome of Interference*

The outcome of Interference No. [1] has a material bearing on the patentability of the claims in this application. Prosecution in this application is SUSPENDED pending a final judgment in the interference.

Applicant should call this case up for action upon termination of the interference.

¶ 23.18 (emphasis added) (reproduced at M.P.E.P. § 2315.01 at 2300-29).

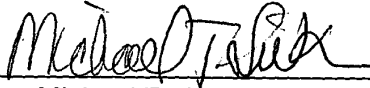
Accordingly, prosecution of this application should be suspended by the Office now.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Date: June 5, 2000

By: 
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